

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TS DMB

Food and Drug Administration

21 CFR Part 573

Display Date \_\_\_\_\_  
Publication Date 2  
Certifier SKese

[Docket No. 02F-0327]

**Food Additive Permitted in Feed and Drinking Water of Animals; Feed-Grade Biuret**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for food additives to provide for the safe use of feed-grade biuret in lactating dairy cattle feed. This action is in response to a food additive petition filed by ADM Alliance Nutrition, Inc.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*; written objections and request for hearing should be submitted by *[insert date 60 days after date of publication in the Federal Register]*

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Sharon Benz, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6656.

**SUPPLEMENTARY INFORMATION:**

cv0322

**02F-0327**

**NFR**

## **I. Background**

In a notice published in the **Federal Register** of August 28, 2002 (67 FR 55269), FDA announced that a food additive petition (FAP 2248) had been filed by ADM Alliance Nutrition, Inc., 1000 North 30th St., P.O. Box C1., Quincy, IL 62305–7100. The petition proposed to amend the food additive regulations in Part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the use of feed grade biuret in the diets of lactating dairy cows. The notice of filing provided for a 75-day comment period on the petitioner's environmental information. No substantive comments have been received.

## **II. Conclusion**

FDA has evaluated data submitted by the sponsor of the petition and concludes that the data establish the safety and functionality of feed-grade biuret for use as proposed.

## **III. Public Disclosure**

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

#### **IV. Environmental Impact**

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **V. Objections and Hearing Requests**

Any person who will be adversely affected by this regulation may at any time on or before [*insert date 60 days after date of publication in the **Federal Register***], file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 573**

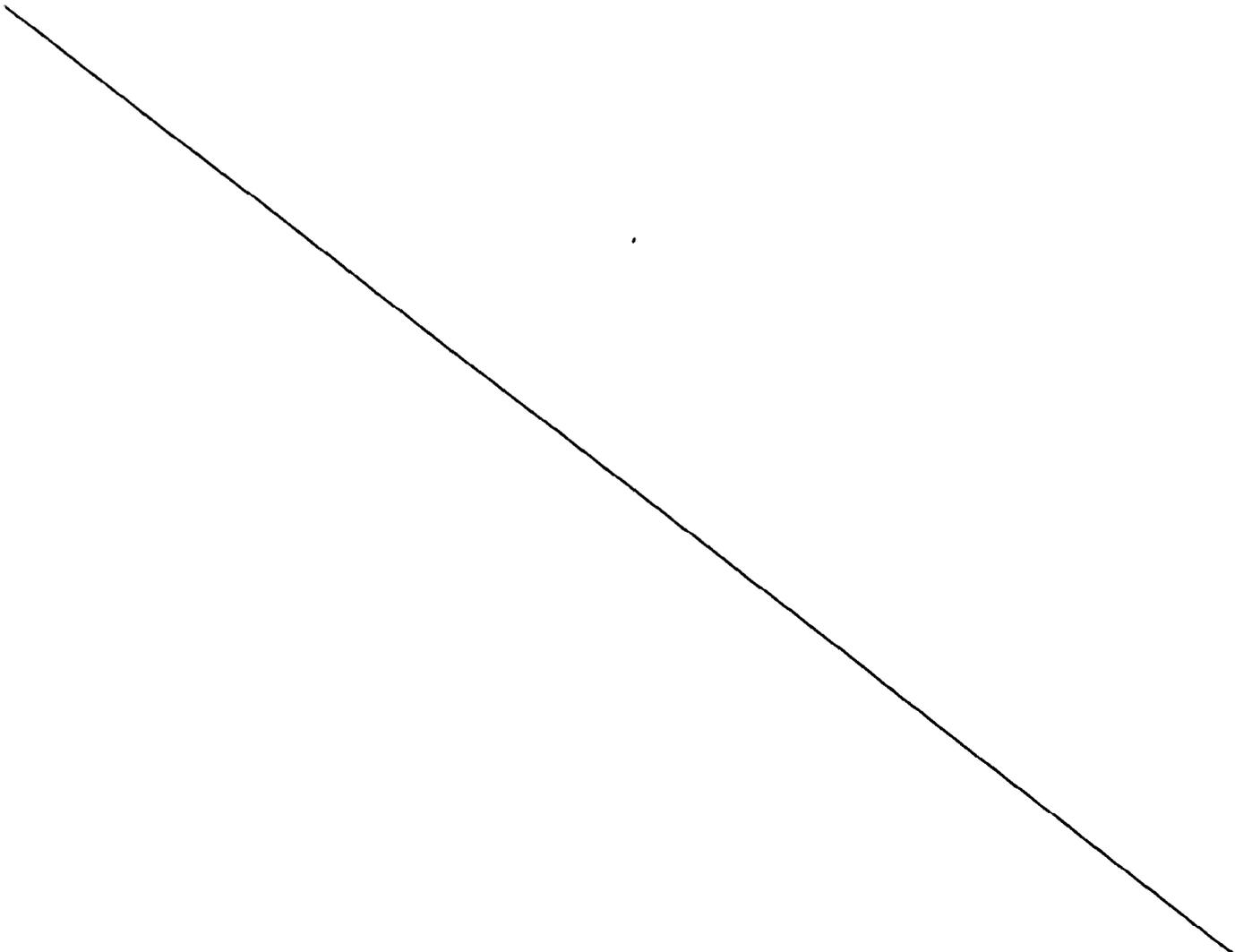
Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

**PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS**

1. The authority citation for 21 CFR part 573 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.



**§ 573.220 Feed-grade biuret.**

2. Section 573.220 *Feed-grade biuret* is amended by removing paragraph (c)(1)(iii).

Dated: 5/14/03  
May 14, 2003.

*SFS/A*

Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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